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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/627,383 07/28/00 MATSUDAIRA

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021005 HM12/1106
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EXAMINER

COOK, L

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

11/06/01

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/627,383

Applicant(s)

MATSUDAIRA ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 16-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☒ Claim(s) 11-15 is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

1. Applicants' election of Group II (claims 11-15) in Paper #8, filed 10/01/01 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

2. Currently, claims 1-26 are subject to Restriction and Election Requirement. Claims 1-10 and 16-26 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 11-15 are pending and under examination.

Priority

3. Provisional application no. 60/061,801 was filed more than one year to the filing of the instant application. (10/14/97). Benefit to this application is not granted. See MPEP 35 USC 119- 3 (e)(1). [as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director.]

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.
6. The information disclosure statement filed 3/22/01-Paper #6, has been considered as to the merits prior to first action.

Oath/Declaration

7. A new oath or declaration is required because provisional application number 60/061,801, filed 10/14/1997 is not listed under 35 USC 119(e). The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. The use of the trademarks has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Objections

9. Claims 11-15 are objected to under 37CFR 1. 821(d) for failing to recite the SEQ ID NOS in the claims. Therein the actual compositions are not properly recited. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

10. Claims 11-15 is directed to non-statutory subject matter. The invention as claimed reads on an affinity fluorescent expression cassette/vector/molecule, which includes naturally occurring as well as synthetic compositions.

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Nonnaturally occurring compositions are considered to be patentable subject matter with in the scope of 35 U.S.C. 101, but products occurring in nature are considered non-statutory and non-patentable. See Official Gazette, 1077 O.G. 24, April 21, 1987. It is recommended that the claims incorporate the claim language, "isolated" or "purified" to overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 11-15 are vague and indefinite in utilizing the following acronyms: GFP, LEPRAS, Gln, Asp, Ser, Pro, etc. Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance. The initial explanation will convey intended meaning of subsequent abbreviations in the claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsien et al. (WO 97/28261) in view of Tsien et al. (USC Patent #6,066,476) and further in view of (WO 98/36081).

Tsien et al.(WO 97/28261) teach tandem fluorescent protein constructs including GFPs. (affinity fluorescent protein molecules) See abstract and page 14. A first polypeptide binding domain-donor fluorescent protein construct, an acceptor fluorescent protein moiety, and a second polypeptide binding domain-a linker moiety coupling the donor and acceptor (tandem fluorescent protein constructs) are employed to measure enzymatic activity. One of the components of this tandem fluorescent protein construct comprises a cleavage recognition site for an enzyme. (Page 2, lines 25-28). Fluorescence resonance energy transfer measurements can be determined when the donor moiety is excited. (Page 2, lines 16-30). Enzymatic activity assays are utilized to detect both *in vitro* and *in vivo* evaluations. See page 2, lines 16-18.

Tsien et al.(6,066,476) further disclosed that modification in the sequence of Aequorea wild-type GFP could provide products with different excitation and emission spectra's. Several different restriction endonuclease sites are discussed in the patent. See columns 4-6.

Tsien et al.(WO 97/28261) and Tsien et al.(6,066,476) differ from the instant invention in not specifically teaching the reaction sites recited in the claims (i.e. Gln157 and Lys158, etc).

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However, Miesenbock et al. disclosed affinity fluorescent protein expression molecules comprising modified GFP (see figure 5 and page 25) Examples of amino acid substitutions are seen in table 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize various modified GFP sequences as taught by Miesenbock et al. in the GFP tandem constructs of Tsien et al. (WO 97/28261) in view of the modified GFPs of Tsien et al. to produce affinity fluorescent protein molecules because such restriction site modification procedures as taught by Miesenbock et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing endonuclease restriction in GFP sequence production as taught by Miesenbock et al. because fluorescent molecules were taught to be attractive as receptor molecules in many assay systems because of their high sensitivity and ease of quantification. See abstract.

A person of ordinary skill in the art would have been motivated to employ modified GFPs because Miesenbock et al. taught that such restriction modifications would further enhance the ability of the molecules to detect changes in the microenvironment. See page 4, line 35 to page 5, line 1. With respect to the particular restrict site, unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to modify GFP at known restriction sites in order to produce the most optimal configuration useful in the given parameters.

13. For reasons aforementioned, no claims are allowed.

Remarks

14. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

Tsien et al. (WO 92/00388) teach long wavelength engineered fluorescent proteins and their methods of use. Fluorescent molecules are attractive as reporter molecules in many assay systems because of their high sensitivity and ease of quantification (page 1, lines 15-16).

Thastrup et al.(US patent 5,958,713) disclose modified GFP proteins to detect biological activity.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

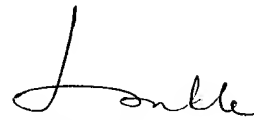


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11/5/01



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